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THE APPLICATION OF 10CFR830.120 IN A BASIC RESEARCH ENVIRONMENT

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Abstract

In this paper, I describe the process of applying the 10 basic criteria of the proposed 10CFR830.120 to a basic research environment like Fermilab and discuss some of the issues associated with the implementation of such a program. I will also discuss some of the differences and similarities between the 18 basic elements of NQA-1 and the 10 criteria of 10CFR830.120 along with the more "philosophical" issues associated with performance versus process-based approach to quality in basic research.

The NQA-1/10CFR830.120 Enigma

During the first 17 years of Fermilab's 22 year history, the laboratory successfully carried out its mission and goals by using good scientific practices, in the absence of a formalized, written QA program. When the requirement for a formally documented QA program was finally imposed on Fermilab, the laboratory voluntarily used NQA-1 as a guidance document, although it was not required by DOE Order 5700.6B. Using a tailored application of just the 18 elements, the good scientific practices were concretized into an institution-wide QA program that was traceable to NQA-1 but did not attempt to redefine *scientific* activities in terms of *nuclear* activities. But despite our efforts at implementation, many times NQA-1 just did not fit the basic research culture. More importantly, it was extremely difficult to define how QA was a value-added component to the mission and goals of the laboratory.

When I first read the 10 criteria of 10CFR830.120, I was stuck by the fact that they were much more user-friendly to a basic research culture than NQA-1.² But having been a quality professional for the last 6 years, I wanted to calibrate my intuitions against the physicists and line management of the laboratory who were not particularly fond of formal QA. Having circulated the document to the physicists in the Fermilab Directorate, a random sample of other physicists, and the line Fermilab QA Officers, they almost unanimously agreed that it more closely fit the basic research culture than NQA-1. Most importantly, they promised to more fully support the Fermilab QA program if it were based upon the 10 criteria. Because there is no

¹ Fermi National Accelerator Laboratory (Fermilab) is operated by Universities Research Association Inc., for the United States Department of Energy (DOE).

² I describe the basic research culture in Mark Bodnarczuk, "Peer Review, Basic Research, and Engineering: Defining a Role for QA Professionals in Basic Research Environments", published in *The Proceedings of The Juran Institute, Inc. - Research and Development Quality Symposium*, June 11, 1991, Newark New Jersey.

national consensus standard for QA in basic research, the laboratory Directorate decided to reissue the Fermilab Institutional Quality Assurance Program with 10 QA criteria that were almost identical to the criteria of the 10CFR830.120.

But over the last year, in numerous discussions with other QA professionals (both pro and con), I began to realize that the relationship between NQA-1 and 10CFR830.120 was characterized by two strange enigmatic questions that demanded explanation. First, how does one explain the fact that the two QA documents are constituted by almost the same content, and yet one is so much more user-friendly to the research culture at Fermilab? Second, if I *personally* owned and operated Fermilab and had to pay for implementing a QA program, why would I choose one document over the other? After a brief summary of the initial process of implementing the new QA program, the goal of the remainder of this paper will be to answer these two questions.

Applying 10CFR830.120 at Fermilab

The process of applying the 10 criteria laboratory-wide was rather straightforward. First, we took the 10 criteria and wrote a revised Institutional QA Program Plan. It contained the same basic content as the previous version but substituted the 10 Fermilab QA criteria for the 18 elements of NQA-1. Second, we set about the task of developing an implementation plan for applying the criteria to laboratory activities. I asked the QA Officers from each Division/Section of the laboratory to develop a question set that if answered carefully, would form the basis of a QA program that complied with the 10 QA criteria. Third, with the input from the QA Officers and the question set that I generated, I finalized them into a Specific Quality Assurance Program (SQAP) Guideline and issued it as an appendix in the Institutional QA Program Plan. Not only does the SQAP guideline serve as the basis for writing laboratory-wide QA programs, it also serves as a calibration point against which the Quality Assurance/Value Engineering Office reviews SQAP's prior to approval.

From its inception, the QA program at Fermilab has tried to take a performance-based approach to quality. Even under the previous NQA-1-based program, Divisions/Sections were required to perform a functional analysis (FA) of all activities, and formulate the FA's in terms of terminal and subordinate objectives.³ When implementing the 10 QA criteria, the functional analysis became the guiding factor for defining which activities should be controlled by a SQAP. The key was to define organizational *functions* as organizational *processes* which could be codified, studied, and controlled. All Divisions/Sections at the laboratory were subsequently required to generate a prioritized list of SQAP's for their areas of responsibilities which included milestone dates for completing all SQAP's. Currently, the plan is to have all SQAP's written and implemented by December, 1991.

The important thing to note here is that this was a consensus building process which included the people that would actually have to live with the new program. On the one hand, this type of consensus building is the way that decisions are normally made within the basic research culture. On the other hand, it is analogous to one of the major tenants of Quality Function Deployment (QFD); having the "customer" give substantial input into producing the item or service that he will eventually be called upon to use. It has been my experience that unless the QA programs developed at basic

³ I discuss the functional approach to defining organizations in Mark Bodnarczuk, "Reductionism, Emergence, and Functionalism; Presuppositions in Designing Internal QA Audits, published in *The Proceedings of the 15th Annual ASQC National Energy Division Conference*, San Antonio, Texas, October 23-26, 1988, p 6 ff.

research laboratories are consensus building processes, they will not be accepted by researchers or other laboratory personnel.

Performance Objectives and Process Definition; A Dialectic Tension

In this section, I will examine the concepts of performance objectives and process definition more carefully and characterize them in terms of a dialectic that cannot be severed without adversely affecting quality. Webster defines *performance* as, "The execution of an action, something accomplished, the fulfillment of a claim, promise." The word *objective* does double duty, having two distinct nuances, both of which are important to the discussion of performance-based QA. The first nuance highlights the end result or "Something toward which effort is directed." When using the word in this way, the focus is on a terminal criterion that guides and vitally constrains the activities and processes that lead to the achievement of the objective. But the second nuance of the word objective raises far more interesting questions in terms of how one *measures* performance. Webster says that when something (like performance) is objective it is "external to the mind." When used in this way, objective means "Expressing or involving the use of facts without distortion by personal feelings or prejudices, relating to or being methods that eliminate the subjective by limiting choices to fixed alternatives requiring a minimum of interpretation." The first meaning of "performance objectives" entails clearly defining criteria or specifications. The second meaning points to the fact that the appraisal of how well they are being met must be motivated by a conscious decision to remove subjective prejudices and objectify the criteria being evaluated. This allows them to be measured by a standard that can be agreed upon by all involved.

We are all interested in obtaining the end product or result we expect, so why do orthodox QA professionals like J. M. Juran claim that one must move back into the "process" in order to achieve performance objectives? Industry discovered that placing emphasis *solely* on the end product actually created quality problems. They learned that they could not inspect quality into a product by rejecting it when it rolled off the assembly line as a completed unit. Not only was the cost of scrap and rework prohibitive, but trying to inspect quality into an item was too late in the process and totally ineffective. The solution was to move further upstream, defining the overall process as a series of sub-processes which led to the finished product. Once the process was clearly defined, Juran claimed that the process and the people performing it must be brought into a state of "self control." I will quote Juran at length on this point:

"Before a person can be in a state of self-control, several fundamental criteria must be met. He must be provided with: 1. Knowledge of what he is *supposed to do*, i.e. the budgeted profit, the schedule, the specification. 2. Knowledge of what he is *doing*, i.e., the actual profit, the delivery rate, the extent of conformance to specification. 3. Means for *regulating* what he is doing in the event that he is failing to meet the goals. These means must always include the *authority* to regulate and the *ability* to regulate either by (a) varying the process under the person's authority or (b) varying the person's own conduct. If *all* the foregoing parameters have been met, the person is said to be in a state of self-control and can properly be held responsible for any deficiencies in performance. If *any* of the parameters has not been met, the person is not in a state of self control, and, to the extent of the deficiency, cannot properly be held responsible."⁴

⁴ See J. M. Juran, editor, *The Quality Control Handbook*, 3rd ed. (New York: McGraw-Hill Book Company, 1979), p 2-13.

Juran's approach can be characterized in terms of a *dialectic tension* between performance and process, with the performance objectives (fitness for use) powerfully constraining the process at every point.⁵ The performance objectives act as heuristics that point to quality problems back in the process, and defining and controlling processes up-front are preventative ways to achieve performance objectives. But what happens if the dialectic between performance and process becomes *skewed* in one direction? I already noted the fallacy of believing that quality can be inspected into a product after-the-fact. But what happens if the *magnification* of process analysis is increased to the point where the performance objectives are no longer the vital constraint, the reason to be? What happens if one becomes so engrossed in the "trees" of the process, that the "forest" of performance objectives is eclipsed from view? When this happens, the dialectic tension between process and performance is destroyed. Placing emphasis *solely* on the process can create quality problems because the absence of performance objectives forces the *entire* process out of control.

Another reason why the quality profession has learned to define and control processes dialectically is because this removes many of the *subjective* elements involved in determining when performance objectives have been met. By *objectifying* the analysis using methodologies like Pareto Analysis and Statistical Process Control many subjective elements and personal interpretations can be eliminated. Over the years, the quality profession has developed these methodologies into a systematic "body of knowledge" as typified in Juran's Quality Control handbook. Much like the high-energy physics culture at Fermilab, the supreme goal of this portion of the QA profession is to *objectify* performance criteria and remove as many of the *subjective* elements as possible.

The success of a dialectic approach to process and performance can be attributed to at least four major things. First, the performance objectives guide the entire process start to finish and define the relative *importance* of the sub-processes which constitute the overall system. Second, each sub-process is defined *uniquely* and manipulated so that it helps to achieve the overall performance objective. There's no "one-size-fits-all" approach to assuring quality. Third, having defined the processes, one must *reflect* upon and *study* them to gain a detailed knowledge of how they can be improved. Finally, one must make sure that the line personnel that execute the process are in a state of self control which makes them *accountable* for achieving the performance objectives.

Unlike Juran's dialectic approach to quality, much of the corporate wisdom in the DOE-based QA culture has been plagued by the tendency to *sever* the process from performance-based criteria. This has been exacerbated by the fact that NQA-1-based QA programs tend to place most of their emphasis on the fine-grained details of "processes" without making explicit reference to the end-product of quality, for example a properly functioning nuclear reactor or high-level waste repository built on time and within budget. I suspect that the repetitive failure to achieve these performance objectives (due to political and technical constraints) has fathered the tacit assumption that achieving these goals may not even be possible.

In addition, the more recent attempts to legalistically impose a one-size-fits-all approach to NQA-1 on basic research and reactors *alike* is in direct conflict with Juran's claim that processes must be *uniquely* defined in terms of performance

⁵ I am using the word dialectic in the sense of a dynamic tension between two interacting forces or elements that cannot be separated without disrupting the function of both components of the system.

objectives.⁶ For example, if a laboratory like Fermilab takes an approach that is similar to Juran's, claiming that NQA-1 must be "tailored" to the performance objectives and mission of the laboratory, paradoxically, this is viewed as recalcitrance toward the principles of "quality." In a culture where compliance is exalted to a *virtue*, quality improvement has been viewed as a *vice*. By de-emphasizing performance objectives and simultaneously venerating the one-size-fits-all approach to process-based QA, quality improvement has been sacrificed. In other words, the dialectic tension between process and performance is severed and process-based QA becomes an end in itself, rather than a means to an end.

Along these lines, the tendency to allow the QA oversight function to usurp line management's authority to define QA policy has driven many organizations out of control as defined by Juran. Not only has there been confusion about how laboratories like Fermilab should interpret and implement quality requirements, but the authority and ability of line management to regulate line processes is a constant point of contention between line management and the QA oversight function. Unless line management actually has the authority and ability to regulate the processes they administer, they cannot be properly held responsible for their deficiencies.

Another serious danger of focusing on process almost to the exclusion of performance is that it can reintroduce many *subjective* elements back into what ought to be an *objective*, measurable approach to quality. Quantitative methods for assessing the effectiveness of QA programs cannot be systematically defined when the focus is on process to the exclusion of performance objectives. Demands that QA become largely "paper" requirements that are not value-added to performance objectives re-introduces a profound sense of subjectivity into the process of assuring quality. As long as we're talking about "paper" and "process" to the exclusion of performance, the number of interpretations of *what* paper is needed and *how much* is enough are a function of the number of auditors that evaluate the organization's activities. When performance is the focus of QA, disagreements between line management and the quality organization are more easily adjudicated by the performance criteria themselves. But in the *subjective* world of paper and compliance-for-compliance-sake, such objective adjudication is no longer possible.

On the one hand, scientists place heavy emphasis on performance, "Judge my quality, but don't ask me to demonstrate how I assure it." On the other hand, QA professional's focus on the fine-grained details of paper and process, "We don't understand the performance objectives of your science, we care about compliance as evidenced by paper." In order to maintain the dialectic tension between process and performance, basic researchers must move toward a more formally documented approach to controlling the processes of scientific practice and QA professionals must view performance objectives as the defining factor of how much paperwork researchers need to assure the quality of their work. Without the dialectic tension between process and performance, scientists cannot provide the adequate controls to assure quality and QA professionals will continue to fail to *intellectually convince* scientists that such controls are value-added to their overall missions. I believe that many of the problems described above may find solutions with a properly implemented QA program that is based upon the 10 criteria of 10CFR830.120 because it focuses our attention back on the dialectic tension between end-results and the processes that help to achieve them.

What are the Differences Between NQA-1 and 10CFR830.120?

⁶ It also fails to recognize that there are quantitative physics differences in the risks involved in reactor and accelerator operations.

The shift from a process oriented to a performance-based approach to quality must be supported by, and originate with, top-level management. The use of the 10 criteria *alone* is not enough to effect change in the heavily "process" oriented environment mentioned above. Only when the management philosophy within which the 10 criteria are embedded is *also* changed is it possible to implement a process-based approach to quality and bring an organization into a state of self control. I believe this change in management philosophy has already begun in the DOE with the requirements of recently issued DOE documents. I will highlight two of the most important philosophical shifts in policy.

The first shift involves two sides of the same philosophical coin: 1) line management responsibility for quality and 2) the problem of "backfitting" by QA auditors. While many QA professionals have paid *lip-service* to the notion that line management is responsible for quality, the QA oversight function often attempts to maintain control over the policy making and approval process. Claiming that line management is responsible to assure quality, and then not allowing them to define and approve the methodologies they use, has led to an inconsistent and schizophrenic image for QA requirements. The problem is that QA professionals just don't *trust* line management to develop QA policies to govern their work. The policy portion of the new DOE Order 5700.6C strongly reaffirms line management's responsibility for quality by requiring that the DOE Program Senior Official (PSO) is responsible to define what the quality requirements are and approve the QA plans developed by the programs they administer. In this scenario, it is the technical arm of DOE Headquarters not the QA oversight function that has responsibility for establishing quality policies and implementation plans.

On the flip-side of the coin, the new DOE Order 5700.6C contains a "backfitting" clause which requires QA oversight organizations to audit organizations against the commitments made between the organization and the DOE PSO. The order states that, "DOE assessment of contractor activities shall be conducted based on the commitments agreed upon between the contractor and DOE as documented in the contractor's approved quality assurance program." If this clause is implemented properly, the role of the QA oversight function is to independently verify that the QA program is being implemented as agreed to with the PSO, not to impose additional requirements that are over and above those already in place. In other words, the QA oversight function can no longer "backfit" QA programs and make management decisions through the mechanism of audit findings. This is especially important because such findings are often based upon subjective interpretations which go far beyond the requirements agreed to by management. Not only does this restore line management authority for QA, it helps to define a clearer role for the QA oversight function as a "feedback" mechanism to management. Defining the QA oversight function as a "feedback" mechanism also helps to eliminate confusing, sometimes contradictory, messages about QA by more clearly defining the DOE *customer* as the DOE PSO, not the QA oversight organization.

A second, equally important, shift in policy was evidenced in Under Secretary Tuck's mandate to cancel many of the DOE Orders issued by DOE Operation Offices. The memo states, "It had been the practice in the past that the Department's field offices issued supplementary orders to contractors clarifying the Department's orders which had been promulgated from Headquarters. Although, in some cases, such a practice may have been deemed advisable because the order, as written, did not lend itself to direct imposition on contractors, the practice is nonetheless considered unsatisfactory in that it can lead to widely varying degrees of implementation by

contractors."⁷ I am not aware of an instance in which the DOE Operations Offices *reduced* the requirements of Orders issued by Headquarters. The tendency is to impose additional requirements that become the *self-defined* responsibilities of Operations Office matrix support personnel.

By having only one version of a DOE Order, and by making sure that line management is responsible to define and approve the implementation of that Order, many of the problems that have plagued QA at DOE laboratories could be eliminated. More importantly for our discussion, these shifts in management philosophy provide a context in which the performance-based approach typified by the 10 criteria can be implemented. Only when the 10 criteria are embedded within this type of management context, do they have a chance of performing as intended. Let me return to the first of the two enigmatic questions mentioned in the first section of this paper. How does one explain the fact that although the 18 elements of NQA-1 and the 10 criteria of 10CFR830.120 are constituted by roughly the same content, that the 10 criteria are much more acceptable to the basic research culture at Fermilab? I will address this question by discussing some of the major similarities and differences between the 18 elements of NQA-1 and the 10 criteria of 10CFR830.120 under two major categories, 1) logical structure and linguistic content, and 2) the problems involved in explicit and implicit agendas. I will also show how these issues are heuristics which point to the *root cause* of the enigmatic question.

In the first category, the logical structure and linguistic content of the 10 criteria are different from NQA-1. The logical structure of NQA-1 is more closely mapped to a construction project than to the performance-based operation of a facility. While the operational and performance objectives are unabashedly espoused up-front in the 10CFR830.120 by dividing the 10 criteria into the three major performance headings (managing, working, and assessing), the operational and performance aspects of NQA-1 that *do* exist are inserted ad hoc in the supplements. The original focus on the construction process, and the long history of NQA-1's development, has produced a document in which the performance-based management controls missing in the original document have been added after-the-fact in the supplements. This is not the fault of the authors, it's a problem that plagues all documents with long developmental and interpreted histories (for example the Bible and the U.S. Constitution). But by modifying the document after-the-fact ("Oh yea, we need to add something about that too"), its complexity is increased and its logical structure becomes fragmented by the ad hoc additions. In regard to the linguistic content of the 10 criteria, much of the deeply entrenched QA jargon that dominates NQA-1 is noticeably absent. One does not have to be a QA professional or speak "QA" jargon in order to understand the content and intent of the 10 criteria. This makes non-QA professionals (the customers) more at home with the document from the very beginning.

In the second category, many of the items that are only *implicitly* stated in NQA-1 become *explicit* requirements in the 10 criteria. For example, although one can implicitly interpret NQA-1 requirements like "non-conformance" and "corrective action" to "mean" quality improvement, the 10 criteria explicitly require a quality improvement program. By explicitly stating that QA programs should have a constantly moving base-line of performance objectives as part of the basic requirements, one does not have to define this ad hoc in supplements like NQA-1 does.

Another example of a requirement that is implicitly stated in NQA-1 but explicitly stated in the 10 criteria is training and qualification of the people doing the work. Rather than burying this requirement in NQA-1 element 2 (QA Program) or

⁷ Memorandum, The Under Secretary of Energy, to Managers, DOE Operations Offices, Acting Manager, Rocky Flats, February 25, 1991.

including it ad hoc in the supplements, the 10 criteria powerfully focuses management's attention on technical competence. This approach is much more directed at carrying out the Secretary of Energy's 10 point initiative which is designed to restore technical competence to line management. Most importantly for basic research environments, the focus on technical competence is one of the most important aspects of the authority structure of the basic research culture.

The 10 criteria also make an explicit statement about the role of self assessment in the assurance of quality. This function is suppressed in NQA-1 which focuses too heavily on independent verification by the oversight organization. The focus on "self" assessment affirms the fact that quality is a line responsibility and not the job of the quality department. It also helps to clarify the role of the QA professional in basic research environments because the primary mechanism for assuring quality is peer review, an activity in which the QA professional is not directly involved.⁸ By teasing these two activities apart into two explicitly defined requirements, the 10 criteria more closely align with the commonly accepted notion of peer review and line responsibility for quality held by the basic research community at Fermilab.

I will now discuss what I believe to be the root cause of the NQA-1/10CFR830.120 enigma. Although the content of NQA-1 and the 10 criteria are roughly the same, the *magnification* of the two documents is cranked up in different places. Although the content of the documents is very similar, the difference in *focus* creates different *images* of how organizations should be managed. Why is this so crucial and how could it have such a profound effect on the overall tone of the document? It's crucial because what people *focus* on tells you what's *important* to them. In the case under discussion, what a QA *standard* focuses on powerfully structures what QA *programs* look like once they are designed and implemented.

One way to illustrate this point is by using a functional approach where terminal objectives (TO's) can only be achieved by successfully executing a number of subordinate objectives (SO's), and the SO's can only be achieved by successfully executing a number of subordinate-subordinate objectives (SSO's). The TO tells you what the performance objective is, the SO's describe the immediate steps needed to achieve it and the SSO's provide more fine-grained clarification about how the SO's are to be accomplished.

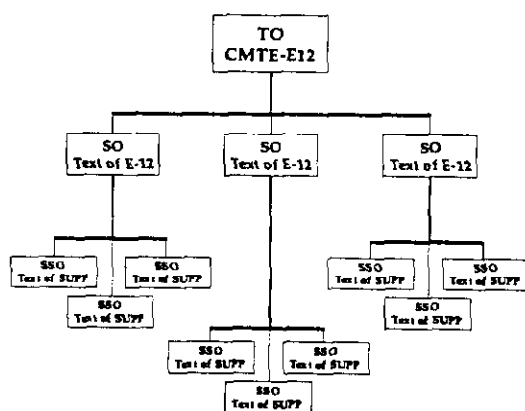


Figure A

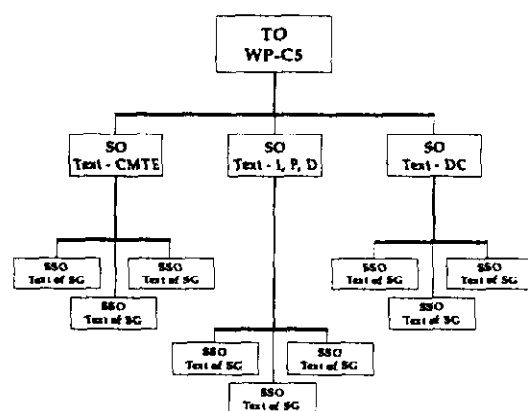


Figure B

⁸ I describe why QA professionals are not part of the peer review process in Mark Bodnarczuk, "Quarks, Leptons, and Quality Assurance" in *Quality Progress*, February, 1991, pp 83-86.

What happens if one characterizes *just the headings* of the 18 elements and the 10 criteria as TO's, the supporting text contained under the headings as the SO's needed to achieve that TO, and the 10CFR830.120 Safety Guide and the 39 Supplements of NQA-1 as SSO's? By making control of measuring and test equipment a TO rather than viewing it as an SO, it *becomes* the performance objective rather than one aspect of doing the work (see Figure A). Making instructions, procedures, and drawings and document control TO's rather than viewing them as SO's, *transforms* them into performance objectives rather than ways of controlling the overall activities of the work. By making non-conformances and corrective action TO's rather than SO's that can lead to quality improvement, the *focus shifts* from continually moving performance objectives, to a more inspection-based notion of rejecting parts that don't work.

On the one hand, with NQA-1, performance-based criteria are buried two or three levels down into the document which is precisely why the logical structure of NQA-1 actually encourages a process-oriented approach to quality. On the other hand, the TO's of the 10 criteria are performance-based at the very *highest* level. This not only powerfully biases the resultant QA programs in the direction of achieving performance objectives, it also makes it much harder for QA professionals to *transform* the fine-grained details of the content of the 10 criteria *into* pseudo-performance objectives for an organization. With the 10 criteria, calibration, instructions, procedures, drawings, and document control are subjugated to their rightful place as part of the overall job (see Figure B). So to conclude, the 10 criteria are more acceptable to basic researchers because the *criteria and the researchers* define the achievement of performance objectives as their Terminal Objective. Although NQA-1 and the 10 criteria *do* contain roughly the same content, only the 10 criteria help to maintain the dialectic tension between process and performance.

The Issue of Owning a QA program

It is common place to hear QA professionals assert that DOE (the customer) wants QA as a requirement. But lurking behind this statement is the mistaken assumption that the oversight function *is* the customer. It has been my experience that more times than not it is the QA oversight function (not the DOE-PSO-customer who controls the program funds) that makes this claim the loudest. The statement that "DOE the customer wants QA" can become a smokescreen used by the QA oversight function to secure more funds for their own organizations. But when the *real* customer (the DOE-PSO) is questioned closely on these matters, his requirements are normally predicated more upon the achievement of the performance objectives of the programs he administers. When the PSO is asked how much of a QA organization he needs, his response is understandably, "only enough to assure that the performance objectives of the program are achieved."

This scenario leads to the second enigmatic question mentioned earlier in the paper, "If I *personally* owned and operated Fermilab with my own financial resources and had to pay for implementing a QA program, why would I choose one document over the other?" Speaking for myself, if it were *my* money that was used to fund QA I would focus upon those areas that had the highest risk of failure. I would want to isolate those processes that were most crucial to achieving the performance objectives of the program and put my controls there. When viewed this way, QA is transformed into an indispensable, *value-added* part of the process of doing science. When one depends on *truly* value-added parameters, then there is no need to appeal to naive arguments based on compliance-for-compliance-sake.

But will there be a need for the QA professional in basic research once line management begins to *really* own the QA program? Frank M. Gryna of the Juran

Institute says "Yes, there will be a quality department."⁹ As I have pointed out elsewhere, the QA professional will be called upon to assume a number of *truly* value-added roles.¹⁰ He will act as *consultant* who advises line management on the appropriate management controls. He will act as a *mediator*, who conceptually translates between the languages of the science performed at his laboratory and orthodox QA methodologies. He will act as *process facilitator* providing guidance on how to implement the 10 QA Criteria in a performance-based way. He will assume the role of *trainer* who provides the pedagogic context in which the expertise of technical personnel and the principles of QA and management are brought *together* in a way that transfers QA activities to line management. Finally, as *oversight function*, he must understand and respect the self-defined boundaries of authority and expertise in science and integrate the appropriate peers into the process of performing QA audits. The QA professional is not a peer to anyone except *other QA professionals* and his competence is predicated on his ability to effectively articulate the principles of QA within the context of the laboratory's research goals, his ability to understand and accept his technical limitations, and his ability to assemble a strong team of technical personnel to help him carry out his responsibilities. In their more quiet and reflective moments, many of the *best* QA professionals that I interact with long to have the type of credibility and sense of pride that this type of truly value-added role will produce. Only then, will they be viewed (and view themselves) as a productive part of the laboratories where they work.

⁹ See Frank M. Gryna, "The Quality Director of the 90's" in *Quality Progress*, April, 1991, p 37 ff.

¹⁰ See Mark Bodnarczuk, "Peer Review, Basic Research, and Engineering; Defining a Role for QA Professionals in Basic Research Environments", published in *The Proceedings of The Juran Institute, Inc. - Research and Development Quality Symposium*, June 11, 1991, Newark New Jersey.